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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,402

07/30/2003

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1066

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06/04/2008

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

06/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,402	Applicant(s) FLAHERTY, PATRICE	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 01/17/2008, 02/13/2008, and 05/28/2008, amended claim(s) 1, 7, 24, and 30-32 and withdrawn claim(s) 12-23 is/are acknowledged. The current rejections of the claim(s) 1-11 and 24-32 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-11 and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Propp (US 5,919,146) in view of Prager (US 4,257,416).

4. For claims 1, 2, 4, 5, 7, 8, 10, 24, and 26, Propp discloses a multi-channel bodily-fluid handling device (as best seen in Figure 1), comprising:

- a main tubing segment (78) for the passage of bodily fluids;
- an indicator unit (48 and 20) and an access port (30) disposed in fluid communication with said main tubing segment and in a branched relationship to each other, wherein both the indicator unit and access port are associated with respective connective tubing conduits or legs (44 and 32, respectively), and wherein said indicator unit comprises a fluid volumeter chamber (48 or 56) adapted for indicating fluid volume (column 2 lines 7-11 and column 3 lines 36-58);

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- a clamp (74) operably engaging said main tubing segment for selectively blocking fluid; and
- an air-permeable liquid-impervious membrane (60) disposed in said indicator unit (column 3 lines 36-41 and column 4 lines 11-21),
- wherein said fluid volumeter is disposed between said main tubing segment and said at least one air-permeable liquid-impervious membrane (as best seen in Figure 1).

5. For claims 3, 6, 9, and 11, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit is disposed in removable fluid communication with said main tubing segment via a second clamp (64) or via disassembly.

6. For claims 25 and 31, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a connector (46) disposed in fluid communication with said main tubing segment, disposed in removable fluid communication with said indicator unit via a third clamp (54) or via disassembly, and between said clamp and said indicator unit and said port (as best seen in Figure 1).

7. For claim 27, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a collector conduit (56, or 68) disposed in fluid communication with said main tubing segment via said indicator unit tubing conduit and disposed in fluid communication with said indicator unit.

8. For claim 28, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit comprises a volumeter conduit (66) disposed in fluid communication with said collection conduit and disposed in fluid communication with said volumeter conduit.

9. For claim 29, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a port (62) disposed between said collector and volumeter conduits.

10. For claims 30 and 32, Propp discloses a multi-channel bodily-fluid handling device, further comprising: said access port tubing conduit or leg disposed in fluid communication with said main tubing segment and in a branched relationship to a collector tubing leg, and wherein said access port is disposed on said access tubing segment.

11. Thus for claims 1-11 and 24-32, Propp discloses the multi-channel bodily-fluid handling device as set forth above, except for expressly disclosing the clamp operably engaging the main tubing segment and adapted to selectively block and unblock fluid flow in both directions therethrough. Prager teaches multi-channel bodily-fluid handling device (as best seen in Figure 1) configured for introducing fluids into a patient and permitting withdrawal of blood samples (Abstract), comprising *inter alia*: a clamp (52) operably engaging a main tubing segment (16) and adapted to selectively block and unblock fluid flow in both directions therethrough (Abstract, column 1 lines 10-15, and column 2 lines 12-19). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Propp and Prager. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the

multi-channel bodily-fluid handling device as taught by Propp with the multi-channel bodily-fluid handling device as taught by Prager to achieve the predictable results of increasing the efficacy of a multi-channel bodily-fluid handling device to control fluid flow therethrough.

Response to Arguments

12. Applicant's arguments with respect to claims 1-11 and 24-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736